

Application No. 09/687,384
Attorney Docket No. 09487.0001

REMARKS

In the Office Action, the Examiner indicates that claims 1 and 4-7 are pending in this application. With entry of this response, claim 1 is amended and no claims are added or canceled. Thus, claims 1 and 4-7 remain pending.

Applicants again request that claim 1 be amended as shown in the claim listing. The Examiner refused Applicants' request filed on May 6, 2004, to enter this amendment, without explanation. Applicants respectfully contend that this amendment "will place the application either in condition for allowance or in better form for appeal" as required. M.P.E.P. 714.12. In fact, the narrower scope of the amended claims focuses the issues for appeal and does not require any new searching by the Examiner. Thus, the amendment can and should be entered.

The fact that the Examiner simply does not believe that the amended claims are patentable is not a reasonable basis for denying the entry of Applicants' amendment. Moreover, if the Examiner refuses to enter this amendment, Applicants will be denied a fair opportunity to appeal the Examiner's interpretation of the "consisting essentially of" claim language as it is being applied to the teachings of Buzas. Accordingly, Applicants have presented the identical claim amendment with this paper and respectfully request that the Examiner enter the amended claims.

The Claims Are Not Obvious Over Buzas et al.

In the Advisory Action, the Examiner maintains the rejection of claims 1 and 4-7, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Buzas et al. (RO 92436), for the reasons made of record. Advisory Action, page 2. The Examiner previously stated that Buzas describes a composition comprising a carbonic

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anhydrase inhibitor and a beta-blocker to treat gastritis, gastro-duodenitis, and gastro-duodenal ulcers. Final Office Action, pages 2-3. The Examiner also argued that Applicants' claims reciting a composition "comprising" (S)-pindolol did not exclude the combination with carbonic anhydrase inhibitors. *Id.*, page 3.

In response to the final Office Action, Applicants amended the claims to exclude the combination of carbonic anhydrase inhibitors and pindolol that is allegedly described by Buzas. The amended claims recite a composition "consisting essentially of an effective amount of S(-) pindolol."¹ The Examiner notes that the language "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. M.P.E.P. § 2111.03 (citing *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976)). According to the Examiner, "it does not appear that the addition of the carbonic anhydrase inhibitor of Buzas et al. would materially change the characteristics of applicant's invention." Advisory Action, page 2.

Applicants respectfully disagree. Buzas teaches that carbonic anhydrase inhibitors, when used in combination with certain other specified compounds (including some beta-blockers like pindolol), provide a synergistic effect. Buzas' synergistic compositions contain a carbonic anhydrase inhibitor and a beta-adrenergic blocker selected from among propranolol, atenolol, pindolol, timolol, oxprenolol, acebutolol, or metoprolol in a weight ratio of 1.37 to 231. Buzas, page 2. Buzas states, "[t]he object of the present invention is to obtain a synergistic pharmaceutical composition . . .

¹ As noted above, the Examiner refused to enter this amendment.

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[through the] selection of ingredients and the mixture ratio thereof." *Id.* Each of Buzas' claims are also explicitly limited to "synergistic" combinations. Achieving synergy appears to be Buzas' whole basis for describing the use of such combination therapies.

According to Buzas' teachings, the addition of a carbonic anhydrase inhibitor would materially alter a composition "consisting essentially of an effective amount of (S)-pindolol" by producing a synergistic effect different from the effect of (S)-pindolol alone. Given this synergy, Applicants contend that the addition of carbonic anhydrase inhibitors would materially affect the basic and novel characteristics of Applicants' claimed invention. As the Examiner acknowledges, any elements having such an affect are excluded by a claim that recites "consisting essentially of." Thus, carbonic anhydrase inhibitors are properly excluded from the presently amended claims. And nothing in the cited prior art teaches or suggests the use of a composition that does not include carbonic anhydrase inhibitors. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claims 1 and 4-7, under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

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Respectfully submitted,

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By:



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